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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,576

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Robert James Nash

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27557

7590

03/23/2010

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EXAMINER

GOUGH, TIFFANY MAUREEN

ART UNIT

PAPER NUMBER

1657

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,576	<b>Applicant(s)</b> NASH ET AL.	
	<b>Examiner</b> TIFFANY M. GOUGH	<b>Art Unit</b> 1657	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 10-19 and 21-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of species pyrrolidine in the reply filed on 11/2/2009 is acknowledged. However, upon further consideration, the previous election of species is hereby withdrawn.

### ***Withdrawn rejections***

#### ***Double Patenting***

Claims 1-9, 20 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6,12-15, 19-21 and 25 of copending Application No. 10506575 has been ***withdrawn*** in light of applicants abandonment of copending Application No. 10506575.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 previously rejected under 35 U.S.C. 102(b) as being anticipated by Karuza et al (J. Pharmaceut. And Biomed. Analysis 1996) is ***withdrawn*** in light of applicants amendment filed 11/4/2008.

***New rejections necessitated by amendment***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and dependent claims 2-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for herbal medicines which comprise phytochemicals selected from the group consisting of that which is exemplified in claim, does not reasonably provide enablement for extracting the claimed phytochemicals from any herbal medicine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. One of skill in the art would not be able to practice the claimed method unless the herbal medicine contained the claimed polar extracts.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and dependent claims 2-9 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step which correlates the characterizing to the quality of an herbal medicine. As currently claimed, there is no step which the quality is actually monitored and how the characterizing step relates to the quality of the drug.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Elbein (5021427).

Applicant claims a method comprising providing a sample of herbal medicine, extracting the sample with a polar solvent to produce an extract of polar phytochemicals and a non-polar residue and characterizing the phytochemical. Applicants claim the extract to be fractionated prior to characterization. Applicants claim fractionation by ion-

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exchange chromatography and gas-liquid chromatography (GLC) and derivitization prior to GLC.

Elbein teaches extracting seed material with methanol to produce a polar phytochemical, specifically pyrrolizidine alkaloids, purifying the extract with ion-exchange chromatography and fractionating the product by TLC and GC with derivitization (col. 9, lines 59-31, esp. col. 9, lines 59-68, col. 10, lines 8-12 and 28-31). Elbein teaches characterizing the extract (col.9-11).

Thus, the reference anticipates the claimed subject matter.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of each of WO 99/34810, Abidi (Journal of Chromatography, 2001) and Khwaja et al. (US 6113907) in view of Elbein (US 5021427) supported by Karuza et al. (J. of Pharm and Biomed. Analysis, 1996).

Applicant claims a method comprising providing a sample of herbal medicine, extracting the sample with a polar solvent to produce an extract of polar phytochemicals and a non-polar residue and characterizing the phytochemical. Applicants claim the extract to be fractionated prior to characterization. Applicants claim fractionation by ion-exchange chromatography and gas-liquid chromatography (GLC) and derivitization prior to GLC.

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WO 99/34810 teaches a method comprising providing a sample of herbal medicine, extracting the sample with a polar solvent to produce an extract of phytochemicals and a non-polar residue and characterizing the phytochemical. Applicants claim the extract to be fractionated prior to characterization. Applicants claim fractionation by chromatography methods, scavenging of non-ionic residues by subjecting the residue to hydrophobic interaction (HIC) and/or reverse-phase chromatography (RPC) and fractionation of the scavenged extract by HPLC (p.7-10, p. 11-45).

Abidi teaches extraction, fractionation, derivitization and chromatography methods used for the analysis of plant extracts. Abidi teaches providing a sample of herbal medicine, extracting the sample with a polar solvent to produce an extract of phytochemicals and a non-polar residue and characterizing the phytochemical. Applicants claim the extract to be fractionated prior to characterization. Applicants claim fractionation by chromatography methods, scavenging of non-ionic residues by subjecting the residue to hydrophobic interaction (HIC) and/or reverse-phase chromatography (RPC) and fractionation of the scavenged extract by HPLC (p.176-198).

Khwaja teach a method for monitoring a herbal medicine comprising providing a sample of an herbal medicine, extracting with polar solvents to produce polar phytochemicals including alkaloids and characterizing the extraction (col. 2, lines 40-51, col. 3, lines 23-27, 47-58, col. 9, lines 1-20, col. 10, lines 10-15, 58-60, col. 12, lines 60-65). They further teach fractionation by various known methods in the art such as



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chromatography methods including, GC, HPLC, RPC as well as scavenging by RPC (col. 11, lines 50-55, col. 14, lines 64-67, col. 17, lines 10-33, col. 18, lines 5-10, col. 19, lines 40-45, col. 20, lines 5-18, 59-60, col. 22, lines 30-36). They teach that the characterizing is important in determining quality for use as a pharmaceutical grade product and for insuring quality of the drug consistent with use as human or veterinary prophylactic or therapeutic agents (col. 12, lines 25-36).

The above references do not teach the polar phytochemicals pyrrolidine, piperidine, pyrrolizidine, indolizidine, tropane and nortropane alkaloids.

It would have been obvious to one of ordinary skill in the art at the time of the invention to extract of naturally-occurring plant constituents because the extraction methods taught by the references can be used to extract polar phytochemicals such as those claimed. Further, the claimed methods for extracting, fractionating and characterizing the claimed phytochemicals are all routine in the art for the claimed purpose, i.e. extraction, fractionation and characterization of plant materials, thus, the method would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the claimed invention. Nevertheless, Elbein teaches extracting seed material with methanol to produce a polar phytochemical, specifically pyrrolizidine alkaloids, purifying the extract with ion-exchange chromatography and fractionating the product by TLC and GC with derivitization (col. 9, lines 59-31, esp. col. 9, lines 59-68, col. 10, lines 8-12 and 28-31). Elbein teaches characterizing the extract (col.9-11).

Karuza is relied upon for the teachings of analyzing the quality and extracts of herbal medicines using chromatography methods.

### ***Conclusion***

NO claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY M. GOUGH whose telephone number is (571)272-0697. The examiner can normally be reached on M-F 8-5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/  
Primary Examiner, Art Unit 1657

/Tiffany M Gough/  
Examiner, Art Unit 1657